



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,600	03/24/2006	James Wilson	UPN-P3230USA	6834
270	7590	04/09/2009		
HOWSON & HOWSON LLP 501 OFFICE CENTER DRIVE SUITE 210 FORT WASHINGTON, PA 19034			EXAMINER EPSP SMITH, JANET L	
			ART UNIT	PAPER NUMBER
			1633	
			MAIL DATE	DELIVERY MODE
			04/09/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/573,600

**Applicant(s)**

WILSON ET AL.

**Examiner**

Janet L. Epps-Smith

**Art Unit**

1633

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32, 43, 45 and 59-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32, 43, 45 and 59-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 32, 43, 45, and 59-66 are presently pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Response to Arguments***

***Claim Rejections - 35 USC § 102***

3. The rejection of claims 32, 43, 45, and 59-61 under 35 U.S.C. 102(e) as being anticipated by Gao et al. (US 7198951; citations given from issued US Patent) or under 35 USC 102(a) as being anticipated by Gao et al. (WO03/052052), is withdrawn in response to Applicant's amendment.
4. The rejection of claims 30 and 32, 43, 45, and 59-61 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7198951, is withdrawn in response to Applicant's amendment.

***Claim Rejections - 35 USC § 112***

5. Claims 32, 43, 45, 59-61 remain rejected and claims 65-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the following: "The AAV according to claim 59, wherein said AAV further comprises a minigene having AAV inverted terminal repeats and the heterologous gene operably linked to regulatory sequences which direct its expression in a host cell." The use of the term AAV as set forth in this claim is vague and indefinite since claim 59 recites only AAV9 and "AAV capsid." If Applicants are referring to the

"non-naturally occurring adeno-associated virus" of claim 59, the claims must be amended to reflect that the term AAV as recited in claims 32, 43 and 45 clearly is limited to the "non-naturally occurring adeno-associated virus" of claim 59.

Claims 59-62, and 65-66 are also vague and indefinite to the extent that the claims recite "an AAV9 capsid," and then further recite the term "the AAV capsid." It is unclear if "the AAV capsid," recited in these claims is intended to refer to the "AAV9 capsid," previously recited in these claims.

6. The previously grounds of rejection of claim 61 under 35 USC 112, 2<sup>nd</sup> is withdrawn in response to Applicant's amendment. However, due to dependency of claims 61-62 on claim 60, claims 61-62 are rejected for the same reasons as claim 60.

7. Claims 63-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 63 recites the limitation "said rAAV" in claim 60. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 64 recites "[w]herein the transgene is selected from the group consisting of: low density lipoprotein (LDL) receptor, high density lipoprotein (HDL) receptor, the very low density lipoprotein (VLDL) receptor and scavenger receptors." This phrase is vague and indefinite since the transgene appears to refer to a single gene, however the term "scavenger receptors," refer to multiple genes.

***Claim Objections***

10. Claim 66 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claim 66 recites wherein the AAV capsid is at least 90% identical to the amino acid sequence of SEQ ID NO: 123 over amino acids 1 to 736, however claim 65 requires that the AAV capsid is at least 95% identical to amino acids 203 to 736 of SEQ ID NO: 123. Claim 66 appears to broader in scope than claim 65 since claim 66 reads on wherein the AAV capsid is only 90% identical to the amino acids of 203 to 736.

11. Claims 32, 43, 45, and 59-66 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/  
Primary Examiner, Art Unit 1633

